SEALED

FILED

NOV 14 2016

CLERK, U.S. DISTRICT CLERK
WESTERN DISTRICT OF TEXAS
BY

DEPUTY

UNITED STATES DISTRICT COURT
FOR THE WESTERN DIVISION DISTRICT OF TEXAS
SAN ANTONIO DIVISION

SEALED I, **Plaintiffs,**	§	**Civil Action No.** SA16CV1140XR
	§	**FILED *IN CAMERA* AND UNDER SEAL**
	§	**Pursuant to 31 U.S.C. § 3730(b)(2) and Tex. Hum. Res. Code § 36.001**
v.	§	
SEALED II, **Defendants.**	§	

FILED UNDER SEAL

(ATTENTION SEAL CLERK)

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA; and THE STATE OF TEXAS; and SLAVISA GASIC, individually,

Plaintiffs,

v.

ONCOLOGY SAN ANTONIO, P.A.; and JAYASREE N. RAO, M.D.

Defendants.

FILED IN CAMERA AND UNDER SEAL PRUSANT TO 31 U.S.C. § 3730(b)(2) and TEX. HUM. RES. CODE § 36.102(b)

CIVIL ACTION NO. _____

PLAINTIFF'S ORIGINAL COMPLAINT PURSUANT TO, 31 U.S.C. " 3729-3732, FEDERAL FALSE CLAIMS ACT and TEX. HUM. RES. CODE ' 36.001, et seq.

JURY TRIAL DEMAND

COMPLAINT FOR VIOLATION OF FALSE CLAIMS ACT (31 U.S.C. ' 3729 *et seq.*) and TEXAS MEDICAID FRAUD PREVENTION ACT (Tex. Hum. Res. Code ' 36.001, *et seq.*)

Pursuant to 31 U.S.C. § 3730(b)(1) and TEX. HUM. RES. CODE § 36.102, Relator, Slavisa Gasic, M.D., for himself and on behalf of the United States of America and the State of Texas, by his attorneys, Correro & Leisure, P.C., brings this civil action under the federal False Claims Act and the Texas Medicaid Fraud Prevention Act and would show the following:

INTRODUCTION

1. This case involves fraudulent claims for chemotherapy, oncological treatment services, and diagnostic tests that were performed without medical necessity or justification and

falsely submitted to Medicare and Medicaid for payment by Dr. Jayasree Rao ("Rao") and Oncology San Antonio, P.A. ("OSA"). Specifically, Rao and her clinic engaged in a scheme whereby government-funded health care programs were billed for services that were medically unnecessary and/or provided in violation of medical and program guidelines.

2. Additionally, Rao and her clinic participate in various unlawful kickbacks schemes. Such actions constitute a violation of the federal Anti-Kickback Statute. 42 U.S.C. §1320a-7b(b).

3. Through the above and other actions, Rao and her clinic intentionally defrauded the federal government and the State of Texas by improperly submitting or causing to be submitted claims for payment, then retaining the payments to which they were not entitled. To support his claims for this fraudulent conduct, Relator alleges as follows:

PARTIES

4. Relator, Slavisa Gasic, M.D. ("Gasic") is a citizen of the State of Texas. He resides in San Antonio, Texas.

5. Defendant, Oncology San Antonio, P.A. ("Oncology SA" or "Defendant"), is a Texas Professional Association that is headquartered and does business at five locations in San Antonio, Texas and is headquartered at 19288 Stone Oak Parkway, Suite B, San Antonio, Texas 78258.

6. Defendant, Jayasree N. Rao, M.D., is a Texas licensed physician and is the registered agent for Oncology San Antonio, P.A. She resides in San Antonio, Texas.

FILING UNDER SEAL

7. Under the False Claims Act, 31 U.S.C. § 3730(b)(2), and the Texas Medicaid Fraud Prevention Act, TEX. HUM. RES. CODE § 36.102, this Complaint is to be filed *in camera* and remain under seal for a period of at least sixty (60) days and shall not be served on Defendants until the Court so orders.

JURISDICTION AND VENUE

8. This action arises under 31 U.S.C. § 3729 *et seq.*, also known as the False Claims Act ("FCA"), the Texas Medicaid Fraud Prevention Act, and the common law to recover treble damages and civil penalties on behalf of the United States of America arising out of Defendants' violations of the FCA.

9. Under § 3732 of the FCA, this Court has jurisdiction over this case pursuant to 31 U.S.C. § 3732(a), as well as under 28 U.S.C. § 1345.

10. This Court has supplemental jurisdiction over all other claims set forth in this Complaint because these claims are so related to the claims arising under the FCA that they form part of the same case or controversy. 28 U.S.C. § 1367.

11. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a), because Defendants transact business in this District. Defendants regularly conducted business with the State of Texas, and maintained permanent employees and offices in the State of Texas, within this judicial district. Additionally, venue is proper in this district pursuant to 28 U.S.C. § 1391(b)(1)–(2).

12. The facts and circumstances which give rise to Defendants' violation of the False Claims Act have not been publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, or General Accounting Office report, hearing, audit, or

investigation, nor in the news media.

13. Relator is the original source of the information upon which this complaint is based, as that phrase is used in the False Claims Act and other laws at issue herein.

14. Relator brings this action based on his direct knowledge and, where indicated, on information and belief. None of the actionable allegations set forth in this Complaint are based on a public disclosure as set forth in 31 U.S.C. § 3730(e)(4), and Relator is an original source of the facts alleged in this Complaint.

15. At all times, Defendants acted through its agents and employees, and the acts of Defendants' agents and employees were within the scope of their agency and employment. The policies and practices alleged in this complaint were, on information and belief, established and/or ratified at the highest corporate levels of Defendants.

Services Provided at Oncology San Antonio, P.A.

16. Oncology San Antonio, P.A. is a medical facility providing oncology diagnosis, treatment, and care. Oncology San Antonio, P.A. provides a number of services, including chemotherapy, PET imaging, radiation oncology, laboratory services, including blood work and bone and tissue samples.

Fraudulent Conduct and Activities

17. Relator worked at Oncology San Antonio from June 2011 to January 2016 as a salaried, non-owner physician. Relator worked directly for Dr. Rao's professional association from September 2014 to January 2016.

18. During his employment at Dr. Rao's clinic, and escalating in Spring of 2015, Relator witnessed serious deviations from the standard of care for many of Dr. Rao's patients.

19. Dr. Rao submitted false claims in the form of upcoded billing diagnoses. Patients were diagnosed and treated for serious malignancies despite the absence of diagnostic criteria necessary for that diagnosis. This practice was widespread, and a few examples are listed below.

PATIENT 1

20. On one occasion, Relator saw a patient ("Patient 1") and, based on a bone marrow biopsy, diagnosed mild anemia, primarily due to blood loss with iron deficiency. However, on the next follow-up, Dr. Rao told Patient 1 that she had a malignant bone marrow disorder—chronic myelomonocytic leukemia ("CMML") and myelodysplastic syndrome ("MDS").

21. But, Patient 1's bone marrow biopsy did not show any significant abnormality and there was no mention of CMML or MDS. Dr. Rao's diagnosis was made in the complete absence of the diagnostic criteria required for the diagnosis of either condition.

22. Dr. Rao then started treating Patient 1 with several cycles of infused chemotherapy. As a result of the unnecessary infusions, Patient 1 suffered toxicity and developed a serious infection and neutropenic fever that required hospital admission.

PATIENT 2

23. Another patient ("Patient 2") had a bone marrow biopsy showing no substantial abnormalities but a premalignant condition that, under standard medical guidelines, should be monitored only.

24. Yet again, Dr. Rao diagnosed this patient with lymphoma—despite the absence of diagnostic criteria necessary for that diagnosis. Dr. Rao then prescribed and administered

an unnecessary two-year course of chemotherapy. As a result of the chemotherapy, Patient 2 became immunosuppressed and developed an immune system deficiency requiring further medical treatment.

PATIENTS 3 and 4

25. Further, at least two patients ("Patient 3" and "Patient 4") were treated as stage IV lung cancer patients, even though under appropriate medical guidelines they should have been classified as stage II or stage III lung cancer patients. According to the staging requirements provided by the American Joint Committee on Cancer ("AJCC") and the International Union for Cancer Control ("IUCC"), the staging for lung cancer involves estimating the size of the primary tumor, estimating the involvement of regional lymph nodes and estimating the distant metastatic disease presence, such as in the TNM system with an overall stage from I to IV assigned by various groupings of TNM subcategories. *See generally*, THE AJCC CANCER STAGING MANUAL, 7th Ed. (2009). A Stage II lung cancer is diagnosed in the presence of primary tumor and hilar or mediastinal involved lymph nodes on same side with the tumor. Stage III indicates the presence of more widespread mediastinal involved lymph nodes including the opposite side from the primary tumor. Dr. Rao upcoded Patients 3 and 4 from Stage II and III to Stage IV, even though they were clearly Stage II and III under the precise staging requirements for lung cancer and stage grouping.

PATIENT GROUP A

26. In addition to these examples, Relator is aware of other patients ("Patient Group A") with mild anemia and unremarkable bone marrow biopsies with no evidence of MDS who Dr.

Rao still diagnosed with MDS and treated with vidaza or Decitabine. Vidaza is a chemotherapy agent indicated for use in patients with certain subtypes of MDS. The known side effects of vidaza include anemia, hepatotoxicity, renal toxicity and tumors. Decitabine is a cancer medication used to treat MDS and acute myeloid leukemia. Some common side effects of Decitabine (among many others) are pain, nausea, vomiting and insomnia.

PATIENT GROUP B

27. In an even more egregious example, patients ("Patient Group B") with monoclonal gammopathy of undetermined significance (MGUS)—a benign condition for which no treatment is recommended, only monitoring, were falsely diagnosed with myeloma and treated with velcade and other chemotherapy. Patient Group A had no malignancy whatsoever, but were given dangerous and expensive chemotherapy. Velcade is a proteasome inhibitor used to treat multiple myeloma and mantle cell lymphoma. Among the known side effects are peripheral neuropathy (nerve damage), myelosuppression (including decreased production of immune cells and platelets), gastro-intestinal distress, and weakness.

PATIENT GROUP C

28. Another false billing scheme employed by Dr. Rao and her clinic was the use of related billing codes for infusions in the absence of FDA-approved indication.

29. For example, patients ("Patient Group C") with chronic lymphocytic leukemia ("CLL") would be mischaracterized as small lymphocytic lymphoma ("SLL"). Then, Dr. Rao would upcode that misdiagnosis into the generic code for lymphoma. Having then

upcoded Patient Group B to general lymphoma, Dr. Rao would prescribe and administer expensive two-year regimens of Rituximab. The treatments prescribed were not approved for either CLL or SLL. In addition to being expensive and unnecessary, the treatments cause multiple side effects. Rituximab is a monoclonal antibody used to treat certain lymphomas and leukemias. Rituximab is a very expensive medication that is associated with extremely serious, sometimes fatal, adverse effects including cardiac arrest, acute renal failure, immune toxicity, pulmonary toxicity, and bowel perforation.

PATIENT 5

30. Dr. Rao also submitted false claims for drugs that were administered for off-label purposes through inappropriate and excessive treatments of malignancies.

31. One patient ("Patient 5") was being treated for locally advanced head and neck cancer. Patient 5 was treated with TPF chemotherapy and Erbitux. TPF chemotherapy is a combination of Taxotere, Platinol, and Fluorouracil. Due to the serious side effects and mortality risk, the standard protocol for induction chemotherapy is three cycles. But Dr. Rao administered five cycles to Patient 5. This number of cycles was excessive and outside the standard of care, particularly since Patient 5 exhibited a good response to the earlier cycles. Following this, Patient 5 was given weekly treatments of Erbitux for twelve weeks.

32. Erbitux is not indicated for immediate follow-on treatment after induction chemotherapy. There is no standard consolidation chemotherapy with either Erbitux or any other chemotherapy agent that would be administered at this period of time. Patients are treated with Erbitux and or chemotherapy only after signs, symptoms and imaging

showing relapsed disease either in head and neck or metastatic development after primary treatment period and observation interval, to allow patients time to recover. Thus, the twelve-week regimen of post-induction chemotherapy given to Patient 5 is not supported by medical guidelines and does not meet the standard of care. As a result of the unnecessary treatment, Patient 5 suffered toxicity including generalized seizures with seizure attack.

PATIENT 6

33. In another typical false billing practice, Dr. Rao would take patients with stage IV malignancies who were clearly at the end stage of cancer and needed to be in hospice, and give them treatments that were unnecessary and ineffective.

34. As one example, a patient ("Patient 6") had received multiple chemotherapy regimens and developed omental carcinomatosis, which is common at the end of life for cancer patients. Rather than being given palliative care, Patient 6 was unnecessarily treated with Avastin. Avastin is a monoclonal antibody used to treat cancers by slowing the growth of new blood cells. The known side effects of Avastin include hypertenstion, fatigue, infection, increased bleeding, and bowel perforation.

35. In addition to being expensive and unnecessary, the treatment caused a small bowel perforation and Patient 6 was admitted to the hospital and died in worse agony than if she had not been given the unnecessary treatment.

PATIENT GROUP D

36. Additionally, multiple other patients ("Patient Group D") with stage IV malignancies who needed chemotherapy breaks were instead treated with weekly chemotherapy

sessions involving primarily 5FU and gemzar, in some cases for years at a time. 5FU is an antimetabolite used to treat various cancers. Among its known side effects are nausea, vomiting, myelosuppression and cardiotoxicity. Gemzar is a chemotherapy agent used to treat various carcinomas. Among its known side effects are fatigue, vomiting, rash, weakness and insomnia.

37. In another false billing scheme, Dr. Rao made inappropriate modifications to standard chemotherapy regimens in order to increase the frequency of infusions and visits. Standard chemotherapy regimens which are approved for infusions every 2 or 3 weeks were instead split into weekly dosing regimens. These modifications increased the costs associated with office visits and infusions. The modifications also endangered patients, because any deviation from dose and schedule for a chemotherapy regimen has to be tested in phase 3 clinical trials for safety and efficacy.

PATIENT 7

38. One patient ("Patient 7") was being treated for colon cancer with 5-fluorouracil (5-FU) chemotherapy. Rather than the standard treatment of infusions every two weeks, though, Dr. Rao was administering weekly 5-FU doses to Patient 7. This increased the costs that were ultimately submitted to the government, and also gave a potentially ineffective dose to Patient 8.

PATIENT 8

39. Another patient ("Patient 8") was being treated for diffuse large B-cell lymphoma. Patient 8 was given weekly infusions of R-CHOP, even though the standard R-CHOP protocol is one infusion every three weeks. R-CHOP is a combination of five drugs:

rituximab, cyclophosphamide, hydroxydaunomycin, Oncovin, and prednisolone. This increased the costs that were ultimately submitted to the government, and also gave a potentially ineffective dose to Patient 8.

40. All of the practices described above in paragraphs 20–39 unnecessarily and fraudulently inflated the costs of medical treatment and caused false claims to be submitted to the government, which were then paid by Medicare and Medicaid.

Medicare Program

41. In 1965, Congress enacted Title XVIII of the Social Security Act, 42 U.S.C. §1395 et seq., known as the federal Medicare program, which authorizes medical benefits for the elderly, blind and disabled. The Centers for Medicare and Medicaid Services ("CMS"), an agency of the United States Department of Health and Human Services, is directly responsible for the administration of the Medicare program.

42. Medicare reimbursements for health care services are regulated by CMS, which issues mandatory guidelines on what types of health care services are covered and which are non-covered. There are two controlling coverage policies: National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs).

43. The Medicare NCDs are set out in a series of Medicare Benefit Policy Manuals, which detail whether specific medical items, services, treatments, procedures or technologies will be paid for by Medicare in accordance with title XVIII of the Social Security Act and in compliance with Medicare regulations and rulings. LCDs are developed by each Medicare Part B regional carrier to further specify under what clinical circumstances a service is reasonable and necessary.

44. The Medicare Part A/B Administrative Contractor for Texas is Novitas Solutions, Inc. ("Novitas").

Medicaid Program

45. Medicaid was established by Title XIX of the Social Security Act of 1965, 42 U.S.C. §1396-1396v. Medicaid is a jointly-funded federal-state program and enables states such as Michigan to provide medical assistance to persons whose income and resources are insufficient to meet the costs of necessary medical services.

46. Although Medicaid is funded in significant part by the States, the federal government pays a portion of Medicaid costs. The Medicaid program pays for services pursuant to plans developed by the states and approved by the U.S. Department of Health and Human Services ("HHS") Secretary through CMS. *See* 42 U.S.C. §§ 1396a(a)-(b). States pay doctors, hospitals, pharmacies, and other providers and suppliers of medical items and services according to established rates. *See* 42 U.S.C. §§ 1396b(a)(1), 1903(a)(1). The federal government then pays each state a statutorily established share of "the total amount expended ... as medical assistance under the State plan ..." *See* 42 U.S.C. §1396b(a)(1). This federal-to-state payment is known as federal financial participation ("FFP").

47. In Texas, the federal government pays for approximately 43.82 percent of all Medicaid health care serves, while the State of Texas funds the remaining 56.18 percent. Accordingly, all claims or requests for payments submitted to the Medicaid program are subject to liability under both the federal FCA and the Texas Act.

48. All providers who submit claims to the Texas Medicaid program are required to honor

the terms and conditions of the Texas Medicaid Provider Manual, in accordance with the terms of their Enrollment Agreement.

49. In other words, compliance with the terms of the Texas Medicaid Provider Manual is required in order to properly bill for services.

50. In the State of Texas, Medicaid Provider Enrollment Application providers certify that "concealment of a material fact, or pertinent omissions may constitute fraud and may be prosecuted under applicable federal and state law." Texas Medicaid Provider Enrollment Application, at p. 6.5 (available at the Texas Medicaid website and incorporated herein).

51. In Texas, providers further certify that "any falsification, omission, or misrepresentation in connection with . . . claims filed may result in all paid services declared as an overpayment and subject to recoupment." *Id.* Providers also certify that they will comply with the requirements of the enrollment agreement, including "federal laws and regulations relating to fraud, abuse and waste in health care and the Medicaid program." *Id.* at p. 6.2, 6.5. The Texas Medicaid enrollment agreement requires signatories to notify the State of Texas if they fall out of compliance with any of their obligations. *Id.*

52. In summary, the reasons for the diagnostic test must be evidenced in the patient's chart or medical record.

The Anti-Kickback Statute

53. Under the Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b), it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product (including a prescription drug product) for which payment is sought from any federally-

funded healthcare program, including Medicare, Medicaid, and TRICARE.

54. The Anti-Kickback Act is designed to ensure that patient care will not be improperly influenced by inappropriate compensation from the pharmaceutical industry.

55. Every federally-funded healthcare program requires all providers and suppliers to ensure compliance with the provisions of the Anti-Kickback Act and other federal laws governing the provision of healthcare services in the United States.

56. The Anti-Kickback Act prohibits suppliers such as pharmaceutical manufacturers from compensating, in cash or in kind, a health care provider when a purpose of the payment is to influence the provider's prescribing habits, or to gain favor for its product over the product of any competitor.

57. A violation of the Anti-kickback Act is a violation of the False Claims Act.

Violations of the Anti-Kickback Statute

58. Dr. Rao engaged in a kickback scheme with Insys Therapeutics. In January of 2012, the FDA approved Insys Therapeutics, Inc.'s fentanyl drug, Subsys, for the management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and tolerant to opioid therapy for their underlying persistent cancer pain. In an effort to drive sales, Insys paid Dr. Rao to participate in a sham marketing study in exchange for switching patients from generic hydrocodone to prescriptions of Subsys. The Insys pharmaceutical representative accompanied the doctors and nurses as they saw patients to ensure that Subsys was prescribed. Multiple patients who had mild to moderate intermittent or continuous pain already well controlled by lower doses of milder opioids such as hydrocodone were being needlessly switched to Subsys and subjected to much

higher doses and risk of overdose and death.

59. Upon information and belief, Dr. Rao may have also received kickbacks from Genoptix (now owned by Novartis AG). Dr. Rao sent all of her bone marrow biopsies to Genoptix, for testing. In return, Genoptix provided significant marketing assistance, lunches, and computer hardware and servers to Dr. Rao.

Conclusion

60. In summary, the Defendants were engaged in a comprehensive scheme to bill Medicare and Medicaid (as well as private insurers) for as many services and treatments as possible, with complete disregard for whether the services were medically necessary or provided in compliance with program guidelines.

61. Through these actions, Defendants have unlawfully and improperly billed Medicare and Medicaid, and retained taxpayer monies to which they are not entitled.

Count I: Violation of 31 U.S.C. § 3729

62. Relator realleges and incorporates paragraphs 1-61 of this Complaint as if fully set forth herein.

63. In performing the acts described above, Defendants, through their own acts or through the acts of their officers, knowingly and/or recklessly presented, or caused to be presented, false or fraudulent claims for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A).

64. Specifically, Defendants submitted claims for payment to the Medicare and Medicaid programs for services that were not medically necessary; not billed as provided; or provided as a result of unlawful kickbacks.

65. The United States, unaware of the foregoing circumstances and conduct of the Defendants, made full payments, which resulted in its being damaged in an amount to be determined.

Count II: Violation of 31 U.S.C. §3729(a)(1)(B)

66. Relator realleges and incorporates paragraphs 1–65 of this Complaint as if fully set forth herein.

67. In performing the acts described above, Defendants, through their own acts or through the acts of their officers, knowingly made, used or caused to be made or used, a false record or statement material to a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(1)(B).

68. The United States, unaware of the foregoing circumstances and conduct of the Defendants, made full payments which resulted in its being damaged in an amount to be determined.

Count III: 31 U.S.C. §3720(a)(1)(C)

69. Relator realleges and incorporates paragraphs 1–68 of this Complaint as if fully set forth herein.

70. In performing the acts above, Defendants conspired to commit a violation of subparagprah (A), (B) and (G).

71. Specifically, Defendants unlawfully retained and failed to return the overpayments they received as a result of the false and fraudulent billings submitted to Medicare and Medicaid.

72. Accordingly, the United States has been deprived of the use of such monies and has been

damaged in an amount to be determined.

Count IV: Violation of 31 U.S.C. §3720(a)(1)(G)

73. Relator realleges and incorporates paragraphs 1–72 of this Complaint as if fully set forth herein.

74. In performing the acts above, Defendants knowingly and improperly avoided an obligation to pay or transmit money to the United States Government.

75. Specifically, Defendants unlawfully retained and failed to return the overpayments they received as a result of the false and fraudulent billings submitted to Medicare and Medicaid.

76. Accordingly, the United States has been deprived of the use of such monies and has been damaged in an amount to be determined.

Count V: Violation of the Anti-Kickback Statute

77. Relator realleges and incorporates paragraphs 1–76 of this Complaint as if fully set forth herein.

78. By knowingly and willfully offering kickbacks to induce referring physicians to refer hematology and oncology patients to Defendants and her clinics, Defendants violated the federal Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b).

79. Pursuant to the federal Anti-Kickback Statute, any claim that includes items or services resulting from unlawful kickbacks constitutes a false or fraudulent claim for purposes of the federal False Claims Act.

80. Through Defendants' actions, the United States has been damaged in an amount to be determined.

Count VI: Violation of the Texas Medicaid Fraud Prevention Act

81. Relator realleges and incorporates paragraphs 1–80 of this Complaint as if fully set forth herein.

82. This is a *qui tam* action brought by Relator on behalf of the State of Texas to recover double damages and civil penalties under Tex. Hum. Res. Code § 36.001 *et seq*.

83. Tex. Hum. Res. Code § 36.002 provides liability for any person who-

> (1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact: (a) on an application for a contract, benefit, or payment under the Medicaid program; or (b) that is intended to be used to determine its eligibility for a benefit
>
> (2) knowingly or intentionally concealing or failing to disclose an event:
> (A) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of.
> (i) the person, or
> (ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and
> (B) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;
>
> (4) knowingly or intentionally makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning: (B) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;
>
> (5)... knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.

84. Defendants violated TEX. HUM. RES. CODE § 36.002 and knowingly caused false claims to be made, used and presented to the State of Texas by its deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-kickback Act and § 36.002, and by virtue of the fact that none of the claims submitted in connection with its

conduct were even eligible for reimbursement by the government-funded healthcare programs.

85. The State of Texas, by and through the Texas Medicaid program, unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third party payers in connection therewith.

86. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and upon information and belief, also an express condition of payment of claims submitted to the State of Texas in connection with Defendants' conduct. Compliance with applicable Texas statutes, regulations and Pharmacy Manuals was also an express condition of payment of claims submitted to the State of Texas.

87. Had the State of Texas known that false representations were made to both the FDA and to practitioners about the true state of affairs regarding the safety and efficacy of the subject drugs, it would not have paid the claims submitted by healthcare providers and third party payers in connection with that conduct.

88. Defendants did not, within 30 days after it first obtained information as to such violation, furnish such information to officials of the State responsible for investigating false claims violation, did not otherwise fully cooperate with any investigation of the violation, and have not otherwise furnished information to the State regarding the claims for reimbursement at issue.

89. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to TEX. HUM. RES. CODE § 36.101

on behalf of himself and the State of Texas.

90. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

Prayer

WHEREFORE, Relator prays that this Court enter judgment on behalf of the Relator and against the Defendants for the following:

a. That the United States be awarded damages in the amount of three times the damages sustained by the United States because of the false claims and fraud alleged in this Complaint, as the Civil False Claims Act, 31 U.S.C. §3729 et seq. provides;

b. That civil penalties of $5,500 to $11,000 be imposed for each and every false claim that the Defendants caused to be presented to the United States;

c. That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which Relators necessarily incurred in bringing this case;

d. That Relators be awarded the maximum amount allowed pursuant to the False Claims Act;

e. That the State of Texas be awarded damages in the amount of three times the damages sustained by the State of Texas because of the false claims alleged in this complaint, as the Texas Medicaid Fraud Prevention Act provides;

f. That necessary expenses, costs, and reasonable attorney's fees be awarded as provided by the Texas Medicaid False Claims Act;

g. That Relators be awarded the maximum amount allowed pursuant to the Texas Medicaid False Claims Act, and;

h. All other relief on behalf of the Relator or the United States Government to which they may be entitled and that the Court deems just and proper.

Dated Nov. 09, 2016

UNITED STATES OF AMERICA *ex rel.*
Slavisa Gasic, M.D.

Respectfully submitted,

Correro & Leisure, P.C.

By: /s/ Mark A. Correro
Mark A. Correro
Texas State Bar No. 24045702
Lance Leisure
Texas State Bar No. 24048616
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Attorney-in-Charge for Relator

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and foregoing Complaint and Motion to Seal was forwarded via the United States Mail, certified, return receipt requested, by facsimile, or by messenger to the United States Attorney General, the United States Attorney's Office in the Western District of Texas, and the Department of Justice in Washington, D.C. on this the 9th day of November, 2016.

Mark A. Correro

JS 44 (Rev. 08/16)

CIVIL COVER SHEET

SEALED

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

SEALED

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Mark A. Correro, Correro & Leisure, P.C., 2909 Hillcroft Avenue, Suite 350, Houston, TX; (832) 916-3116; info@CorreroLeisure.com

DEFENDANTS

SEALED

SA16CV1140 XR

County of Residence of First Listed Defendant Bexar
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☒ 1 U.S. Government Plaintiff
- ☐ 2 U.S. Government Defendant
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☒ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☐ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
31 U.S.C Sec. 3729 et seq.

Brief description of cause:
Federal False Claims Act case with pendant Texas Medicaid Frad Prevention Act claims.

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
11/09/2016

SIGNATURE OF ATTORNEY OF RECORD
MJ-PMA

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____